

PATENT COOPERATION TREATY

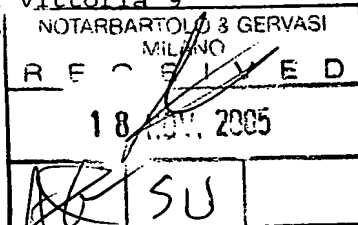
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PCT

From the INTERNATIONAL SEARCHING AUTHORITY

To:

NOTARBARTOLO & GERVASI S.P.A.
Attn. Gervasi, Gemma
Corso di Porta Vittoria 9
I-20122 Milano
ITALY



NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference

4843PTWO/er

Date of mailing
(day/month/year)

17/11/2005

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/EP2005/050728

International filing date
(day/month/year)

18/02/2005

Applicant

ISTITUTO NAZIONALE DELLE MALATTIE INFETTIVE ...

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
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Authorized officer

René De Hoogd

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 4843PTWO/er	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/EP2005/050728	International filing date (day/month/year) 18/02/2005	(Earliest) Priority Date (day/month/year) 19/02/2004
Applicant ISTITUTO NAZIONALE DELLE MALATTIE INFETTIVE ...		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☒ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 2
- ☐ as suggested by the applicant.
- ☒ as selected by this Authority, because the applicant failed to suggest a figure.
- ☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/EP2005/050728

Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.b of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, the international search was carried out on the basis of:

a. type of material

☒

a sequence listing

☐

table(s) related to the sequence listing

b. format of material

☒

in written format

☒

in computer readable form

c. time of filing/furnishing

☒

contained in the international application as filed

☐

filed together with the international application in computer readable form

☒

furnished subsequently to this Authority for the purpose of search

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 G01N33/569 C07K14/35

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G01N C07K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, CHEM ABS Data, Sequence Search, WPI Data, PAJ, MEDLINE, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/005925 A (ISIS INNOVATION LIMITED; LALVANI, AJIT; EWER, KATIE) 15 January 2004 (2004-01-15) claims 1,3,6,11-16,92-94 page 11, line 12 - line 30 page 2, line 28 - page 3, line 4 -----	1-21, 25-33,36
A	WO 02/054072 A (ISIS INNOVATION LIMITED; LALVANI, AJIT) 11 July 2002 (2002-07-11) page 2, line 28 - page 3, line 4 claims 1,3,6,11,13,15 -----	1-21, 25-31
X	WO 99/04005 A (INSTITUT PASTEUR ET AL.) 28 January 1999 (1999-01-28) abstract; claim 21; sequence 8 ----- -/--	3,32,33

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

8 November 2005

Date of mailing of the international search report

17/11/2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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Fax: (+31-70) 340-3016

Authorized officer

Gundlach, B

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/16646 A (CORIXA CORPORATION) 23 April 1998 (1998-04-23) page 122; sequences 95,96 -----	3, 32, 34, 35
A	WO 00/26248 A (ISIS INNOVATION LIMITED) 11 May 2000 (2000-05-11) cited in the application the whole document -----	1-21, 25-31
A	PINXTEREN VAN L A H ET AL: "Diagnosis of Tuberculosis Based on the Two Specific Antigens ESAT-6 and CFP10" CLINICAL AND DIAGNOSTIC LABORATORY IMMUNOLOGY, AMERICAN SOCIETY FOR MICROBIOLOGY, US, vol. 7, no. 2, March 2000 (2000-03), pages 155-160, XP002252151 ISSN: 1071-412X page 157, column 2 -----	1-21, 25-31
A	COCKLE P J ET AL: "Identification of novel Mycobacterium tuberculosis antigens with potential as diagnostic reagents or subunit vaccine candidates by comparative genomics" INFECTION AND IMMUNITY, AMERICAN SOCIETY FOR MICROBIOLOGY, WASHINGTON, US, vol. 70, no. 12, December 2002 (2002-12), pages 6996-7003, XP002252152 ISSN: 0019-9567 the whole document -----	1-21, 25-31
A	ANDERSEN P: "TB vaccines: progress and problems" TRENDS IN IMMUNOLOGY, ELSEVIER, CAMBRIDGE, GB, vol. 22, no. 3, 1 March 2001 (2001-03-01), pages 160-168, XP004255881 ISSN: 1471-4906 the whole document -----	1-21, 25-31

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2005/050728

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-32 (partially), 33 (fully)

Methods of discriminating between latent and active tuberculosis comprising the use of a peptide represented by SEQ ID NO:2

2. claims: 1-32 (partially), 34,35 (fully)

Methods of discriminating between latent and active tuberculosis comprising the use of peptides represented by SEQ ID NO 4 and 6

3. claims: 1-32 (partially), 36 (fully)

Methods of discriminating between latent and active tuberculosis comprising the use of a peptide represented by SEQ ID NO:8

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP2005/050728

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2004005925	A	15-01-2004	AU 2003244856 A1	23-01-2004
			CA 2490172 A1	15-01-2004
			CZ 20050003 A3	18-05-2005
			EP 1520174 A2	06-04-2005
			US 2005208594 A1	22-09-2005
WO 02054072	A	11-07-2002	CA 2433236 A1	11-07-2002
			CZ 20031866 A3	17-03-2004
			EP 1390755 A2	25-02-2004
			JP 2004529320 T	24-09-2004
			NZ 526807 A	24-03-2005
WO 9904005	A	28-01-1999	AU 8123898 A	10-02-1999
			CA 2296419 A1	28-01-1999
			EP 1003870 A1	31-05-2000
WO 9816646	A	23-04-1998	AU 4814497 A	11-05-1998
			BR 9712518 A	24-10-2000
			CA 2268008 A1	23-04-1998
			CZ 9901265 A3	17-11-1999
			EP 0932681 A2	04-08-1999
			JP 2001501832 T	13-02-2001
			KR 2000049101 A	25-07-2000
			NO 991694 A	10-06-1999
			PL 332878 A1	25-10-1999
			TR 9901571 T2	21-10-1999
WO 0026248	A	11-05-2000	AU 6480999 A	22-05-2000
			BR 9915055 A	07-08-2001
			CA 2348475 A1	11-05-2000
			CN 1350546 A	22-05-2002
			EP 1144447 A2	17-10-2001
			ID 29858 A	18-10-2001
			JP 2002532064 T	02-10-2002
			MX PA01004469 A	30-08-2002